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MUIRHEAD AND SATURNELLI, LLC
200 FRIBERG PARKWAY
SUITE 1001
WESTBOROUGH, MA 01581

EXAMINER	
FONTENOT, NIGEL RAI	
ART UNIT	**PAPER NUMBER**
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,421	MAURICE ET AL.	
	Examiner	Art Unit	
	NIGEL FONTENOT	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/2007, 11/20/2006, 10/1/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to the application filed August 4, 2006.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8, 10, 14, 17, 19, 22, 25, and 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 8 recites the limitation "the full strain tensor" in claim line 2. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 10 recites the limitation "the Von Mises (VM) coefficient" in claim line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 14 recites the limitation "the full strain tensor" in claim line 2 and “the components" in claim line 2. There is insufficient antecedent basis for these limitations in the claim.

6. Claim 17 recites the limitation "the Von Mises (VM) coefficient" in claim line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 19 recites the limitation "the elastic modulus" in claim line 5. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 22 recites the limitation "the regularized nonlinear minimization Levenberg-Marquardt (L&M) minimization algorithm" in claim lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 25 and 28-33 do not positively recite any method or process steps. These claims only recite a use for the recited method and do not recite how the use is related to the method or how the method provides the use recited in each claim. Proper correction is needed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-11, 25, 28-30 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Maurice et al. (Noninvasive Vascular Elastography: Theoretical Invesitgation).

12. Addressing claims 1-11, Maurice discloses a method for vascular elastography (see abstract) comprising: providing pre-tissue-motion and post-tissue-motion images in digital form of a vessel delimited by a vascular wall (see p. 165, para 6); said pre-tissue-motion and post-tissue-motion images being representative of first and second time-delayed configuration of said vessel (see p. 165, para 6); partitioning at least portions of both said pre-tissue-motion and post-tissue-motion images into corresponding data

windows (see fig. 1, and p. 166 section "The tissue-motion Model); approximating a trajectory between said pre-tissue-motion and post-tissue-motion images for corresponding data windows (see fig. 1, and p. 166 section "The tissue-motion Model); and using the trajectory for each data window to compute a strain tensor in each data window (see fig. 1, and p. 166 section "The tissue-motion Model); using said strain tensor in each data window to create an elastogram of at least part of said vessel (see abstract, p. 166 section "The tissue-motion Model" and p. 169 1st para on right side); wherein said pre-tissue-motion and post-tissue-motion images are radio-frequency (RF) images (see p. 166 section "The dynamic Imaging-formation model"); wherein said pre-tissue-motion and post-tissue-motion images are part of a sequence of radio-frequency (RF) images (see p. 166-167 sections "The dynamic Imaging-formation model" and "the Lagrangian Speckle model Estimator"); wherein said pre-tissue-motion and post-tissue-motion images are issued from magnetic resonance imaging (MRI), optical coherence tomography (OCT), brightness mode (B-mode) or Doppler-based ultrasound modality imaging (see p. 164 section "Introduction"); wherein providing pre-tissue-motion and post-tissue-motion images in digital form of a vessel includes inducing tissue compression or dilatation on said vessel (see p. 166 section "The Tissue-Motion Model"); wherein inducing tissue dilatation on said vessel is achieved by cardiac pulsation (see abstract and p. 174 section "Results"); wherein said strain tensor is the full strain tensor in at least one of said data windows (see abstract, p. 165 section "Methodology," and p. 167-168 section "The Lagrangian Speckle Model Estimator"); wherein said full strain tensor is computed from three-dimensional or two-dimensional

ultrasound data (see abstract, p. 165 section “Methodology," and p. 167-168 section "The Lagrangian Speckle Model Estimator"), using said full strain tensor to compute the Von Mises (VM) coefficient in each data window (see abstract, p. 165 section “Noninvasive Vascular Elastography," and p. 172 left side); wherein approximating a trajectory for each said data window includes using a Lagrangian speckle model estimator (LSME) (see p. 165 “Methodology" and p. 167 section “The Lagrangian Speckle Model Estimator”).

13. Addressing claims 25, 28-30 and 33, Maurice discloses using the above method for endovascular elastography (see section “Introduction”), using the above method for non-invasive vascular elastography, including microvascular elastography (see p. 165 section “Noninvasive Vascular Elastography” and fig. 5), using the above method for prediction risks of vascular tissue rupture or vascular aneurysms (see p. 177), using the above method for in vivo measurements (see p. 165).

14. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ophir et al. (Ultrasonic Imaging of Tissue Strain and Elastic Modulus In Vivo).

15. Addressing claims 1-4 and 6, Ophir discloses an elastography imaging technique where longitudinal strain is estimated from the analysis of ultrasonic signals obtained from standard medical ultrasound diagnostic equipment. A set of digitized RF echo lines from the tissue region of interest are acquired. The tissue is then compressed by the ultrasonic transducer along the ultrasonic radiation axis and a second set of echo lines

is acquired from the same region of interest. Congruent echo lines are subdivided into small temporal windows which are compared pairwise by using cross-correlation techniques from which the change in arrival time of the echoes before and after compression can be estimated. The longitudinal strain may then be estimated from the differences in arrival times between pre compression and post compression echo lines. The windows are translated in small overlapping steps along the temporal axis of the echo line and the strain calculation is repeated for all depths (see abstract, p. 58, and fig. 2).

16. Claims 34-39 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall (US 6508768).

17. Addressing claims 34-39 and 46, Hall discloses a system for vascular elastography comprising: an ultrasound system for acquiring pre-tissue motion and post-tissue motion radio-frequency (RF) images of a vessel; said pre-tissue motion and post-tissue motion images being representative of first and second time-delayed configuration of said vessel; a controller, coupled to said ultrasound system, i) for receiving said pre-tissue motion and post-tissue motion RF images, ii) for digitizing said pre-tissue motion and post-tissue motion RF images, iii) for partitioning both said pre-tissue motion and post-tissue motion RF images into corresponding data windows, iv) for approximating a trajectory for each said data windows; and v) for using said trajectory for each said data window to compute a strain tensor in each data window;

and an output device coupled to said controller to output information related to said strain tensor in each data window (see fig. 1 and col. 12 line 40-col. 13 line 63; Hall discloses a system that is capable of performing all the functional limitations as above).

18. Addressing claims 35-36, Hall discloses that the reception controller may include analog to digital conversion circuitry. The controller (160) is coupled to ultrasonic transducer element (see col. 13 lines 35-52 and fig. 1).

19. Addressing claims 37-39, Hall discloses an ultrasound instrument including a scanhead, wherein said scanhead includes an array transducer and a single-element oscillating transducer (see (140) and (142) in fig. 1).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir et al. (Ultrasonic Imaging of Tissue Strain and Elastic Modulus In Vivo) in view of Maurice et al. (Noninvasive Vascular Elastography: Theoretical Framework).

24. Addressing claims 12-23, Ophir discloses the limitations of claim 1 above. Ophir discloses computing stress in three dimensions (see p. 55) and computing deformation in blood vessels (see p. 52 left side), but does not explicitly disclose using zero-order and first-order terms of a Taylor series expansion to approximate trajectory. However, Maurice discloses using zero-order and first-order terms of a Taylor-series expansion to approximate trajectory (see p. 166 section "The Tissue-Motion Model"), using said trajectory for each said data window to compute a strain tensor in each data window includes performing a non-linear minimization for each data window by computing a transformation [LT] providing the best match between each of said pre-tissue motion

image and a corresponding window in said post-tissue motion image (see p. 167-168 section “The Lagrangian Speckle Model Estimator”); computing the full strain tensor epsilon (see p. 166 section "The Tissue-Motion Model"); determining an elastogram providing a distribution of each component of the deformation matrix and of the strain tensor (see p. 166 and p. 169); computing a pressure gradient between said pre-tissue-motion and post-tissue-motion images; said pressure gradient being used in determining said elastogram (see p. 156 right side, p. 172 right side, and p. 179); further comprising computing the Von Mises (VM) coefficient in at least some of said data windows (see p. 170-172 section “A new parameter for tissue characterization"); further comprising determining a composite elastogram providing a distribution of the VM coefficient in at least some of said data windows (see p. 176 and fig. 13a); further comprising: providing pressure gradient resulting from blood flow pulsation of said vessel when said pre-tissue motion and post-tissue motion images are taken; and computing the elastic modulus in at least some of said data windows as set forth in instant claim 19 (see p. 171-174); wherein using said trajectory for each said data window to compute a strain tensor in each data window includes solving a minimization equation (see p. 167-168 section “The Lagrangian Speckle Model Estimator”); wherein solving said minimization equation includes using a minimization algorithm (see p. 168), wherein said minimization algorithm is the regularized nonlinear minimization Levenberg-Marquardt (L&M) minimization algorithm (see p. 168); wherein using said trajectory for each said data window to compute a strain tensor in each data window includes solving in a region of interest represented in both said pre-tissue-motion and

post-tissue-motion images for each corresponding said pixels in said pre-tissue motion and post-tissue motion images in digital form (see p. 167-178). Ophir and Maurice are concerned with the same field of endeavor, namely tissue stain imaging. Therefore, it would have been obvious to one of ordinary skill in the art to modify Ophir by using Maurice's methods and expanding the evaluations to three dimensions, as desired by Ophir, since vascular tissue deforms non-uniformly, a Taylor-series expansion accurately approximates small regions of interested for strain modeling and minimizes computation time.

25. Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maurice et al. (Noninvasive Vascular Elastography: Theoretical Framework), in view of Ophir et al. (Ultrasonic Imaging of Tissue Strain and Elastic Modulus In Vivo).

26. Addressing claim 12, Maurice discloses using zero-order and first-order terms of a Taylor-series expansion to approximate trajectory (see p. 166 section "The Tissue-Motion Model"), but does not explicitly discloses using the Taylor-series in three-dimensions. However, Ophir discloses that strain happens in tissue in three dimensions (see p. 55). Ophir and Maurice are concerned with the same field of endeavor, namely tissue stain imaging. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Maurice by expanding the Taylor series to three dimensions since stress happens in three dimensions for tissue that has deformed.

27. Addressing claims 13-23, Maurice discloses using said trajectory for each said data window to compute a strain tensor in each data window includes performing a non-linear minimization for each data window by computing a transformation [LT] providing the best match between each of said pre-tissue motion image and a corresponding window in said post-tissue motion image (see p. 167-168 section “The Lagrangian Speckle Model Estimator”); computing the full strain tensor epsilon (see p. 166 section "The Tissue-Motion Model"); determining an elastogram providing a distribution of each component of the deformation matrix and of the strain tensor (see p. 166 and p. 169); computing a pressure gradient between said pre-tissue-motion and post-tissue-motion images; said pressure gradient being used in determining said elastogram (see p. 156 right side, p. 172 right side, and p. 179); further comprising computing the Von Mises (VM) coefficient in at least some of said data windows (see p. 170-172 section “A new parameter for tissue characterization"); further comprising determining a composite elastogram providing a distribution of the VM coefficient in at least some of said data windows (see p. 176 and fig. 13a); further comprising: providing pressure gradient resulting from blood flow pulsation of said vessel when said pre-tissue motion and post-tissue motion images are taken; and computing the elastic modulus in at least some of said data windows as set forth in instant claim 19 (see p. 171-174); wherein using said trajectory for each said data window to compute a strain tensor in each data window includes solving a minimization equation (see p. 167-168 section “The Lagrangian Speckle Model Estimator”); wherein solving said minimization equation includes using a minimization algorithm (see p. 168), wherein said minimization algorithm is the

regularized nonlinear minimization Levenberg-Marquardt (L&M) minimization algorithm (see p. 168); wherein using said trajectory for each said data window to compute a strain tensor in each data window includes solving in a region of interest represented in both said pre-tissue-motion and post-tissue-motion images for each corresponding said pixels in said pre-tissue motion and post-tissue motion images in digital form (see p. 167-178). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Maurice by expanding to three dimensions since stress happens in three dimensions for tissue that has deformed, as disclosed above.

28. Claims 24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maurice et al. (Noninvasive Vascular Elastography: Theoretical Framework), in view of Hall (US 6508768).

29. Addressing claims 24 and 26-27, Maurice discloses wherein providing pre-tissue-motion and post-tissue-motion images includes acquiring intravascular RF images using a catheter (see p. 164-165 section “Reported Works on EVE”), but does not explicitly disclose collecting cross-sectional and longitudinal data. However Hall states that it would be known to a person skilled in the art to extend two dimensional procedures to three dimensional imaging and processing. Instead of processing echo signal information from points on a scan plane, information from samples within a scan volume will be processed (cross section and longitude). Instead of two dimensional search windows, a three dimensional embodiment will use three dimensional search windows

(see col. 13 lines 20-33). Hall also discloses that a catheter is disposed within a target blood vessel and that said catheter includes an ultrasound transducer which is rotated to provide a circumferential image of the vessel (see paras 3-5). Hall and Maurice are concerned with the same field of endeavor, namely ultrasonic stain imaging. Therefore, it would have been obvious to one of ordinary skill in the art to process collect cross-sectional and longitudinal data from said vessel by sweeping the beam over a predetermined angle to analyze motion in all directions.

30. Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maurice et al. (Noninvasive Vascular Elastography: Theoretical Framework), in view of Cantini et al. (Aminoguanidine and Aortic Wall Mechanics, Structure, and Composition in Aged Rats).

31. Addressing claims 31-32, Maurice does not explicitly discloses phenotyping in animal models using genetic or closing technologies for modeling hypertension. However, Cantini discloses that aortic walls become stiffer with age and this could be caused by changed in wall stress or composition and that this is sometimes found in rats with hypertension (see abstract and p. 947). Therefore, it would have been obvious to use Maurice's method for phenotyping in animal models using genetic or cloning technologies to model hypertension since this disease can be linked from rats to humans (see p. 946-967 in Cantini).

32. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (US 6508768), in view of Maurice et al. (Noninvasive Vascular Elastography: Theoretical Framework).

33. Addressing claims 40-41, Hall does not explicitly disclose a catheter or an ultrasound biomicroscope for non-invasive microvascular elastography measurement. However, Maurice discloses a catheter and ultrasound biomicroscope for non-invasive microvascular elastography measurements (see p. 165). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hall by incorporating a catheter or an ultrasound biomicroscope for non-invasive microvascular elastography measurements since these devices provide better understanding of wall elasticity and allow for identifying hard and soft plaques of the vessel wall.

34. Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (US 6508768), in view of Cantini et al. (Aminoguanidine and Aortic Wall Mechanics, Structure, and Composition in Aged Rats).

35. Addressing claims 44-45, Hall does not explicitly discloses phenotyping in animal models using genetic or closing technologies for modeling hypertension. However, Cantini discloses that aortic walls become stiffer with age and this could be caused by changed in wall stress or composition and that this is sometimes found in rats with hypertension (see abstract and p. 947). Therefore, it would have been obvious modify

Hall by incorporating phenotyping in animal models using genetic or cloning technologies to model hypertension since this disease can be linked from rats to humans (see p. 946-967 in Cantini).

36.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIGEL FONTENOT whose telephone number is (571)270-7032. The examiner can normally be reached on Monday-Friday (7:00a-4:00p).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. F./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768